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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,561	11/07/2001	Guo-Bin Wang	32286-232713	3657

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	PAPER NUMBER
1772	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,561	WANG ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on October 31, 2006 and January 3, 2007 have been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 69-70, 76-82, 84-86, 90-91, and 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 69, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof comprise functional groups to attach or bind physiologically or pharmacologically active agents is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise functional groups to attach or bind physiologically or pharmacologically active agents, but does not teach that acrylamide and/or N,N-dimethylacrylamide are used for this purpose.

Regarding claim 70, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof comprise a drug depot permitting the delivery of drugs from the graft polymer coating is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise a drug depot permitting the delivery of drugs from the

graft polymer coating, but does not teach that acrylamide and/or N,N-dimethylacrylamide are used for this purpose.

Regarding claim 76, the specification does not teach that the graft polymerized coating is formed of pyridine or piperidene. The specification teaches some specific monomers such as 2- or 4-vinylpyridine, 4- or 2-methyl-5-vinylpyridine, and N-methyl-4-vinylpiperidine, but does not teach that any pyridine or piperidene may be used to form the coating as claimed in claim 76.

Regarding claims 79 and 90, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer serve as a tie coat to adhere an additional layer to the substrate is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen to act as a tie coat to adhere an additional layer to the substrate, but does not teach that any of the particular monomers of the Markush groups of claims 76 and 87 are used for this purpose.

Regarding claims 81 and 93, the limitation that the monomers selected from the Markush group of possible monomers

for the coating layer comprise functional groups to attach or bind physiologically or pharmacologically active agents is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise functional groups to attach or bind physiologically or pharmacologically active agents, but does not teach that any of the particular monomers of the Markush groups of claims 76 and 87 are used for this purpose.

Regarding claim 82, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer comprise a drug depot permitting the delivery of drugs from the graft polymer coating is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise a drug depot permitting the delivery of drugs from the graft polymer coating, but does not teach that any of the particular monomers of the Markush groups of claim 76 are used for this purpose.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 64-70 and 71-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al (USPN 6,287,285).

Note before discussing how the reference anticipates Applicant's claims, the broadest reasonable interpretation of a substrate is not limited to one material or one layer of material. Substrate is defined merely as an object or article in which layers of material are applied. The scope of the term substrate would include multi-layered objects or articles, including substrates that comprise coatings.

Regarding claim 64 and 72, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said

substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). The metal device and the base coat over top of the metal device taught in Michal et al combined is a substrate, as that term is broadly interpreted from Applicant's claims. The base coat comprises a binding component, which is formed of a isocyanate compound (col.8, l.14-31), such as the urethane-acrylate taught in example 4 in column 16, lines 49-51). Thus, the substrate comprises copolymers of polyurethane. A plurality of monomer molecules are directly graft polymerized on at least one of the surfaces of the substrate, forming a top coat thereon (col.11, l.5-10). The top coat is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an acrylamide, N,N-dimethylacrylamide, and mixtures thereof (col.8, l.1-6).

Regarding claims 65-66, the medical device is a catheter, guide wire or medical instrument (col.2, l.10-12), and the catheter is specifically a PTCA catheter (col.5, l.53-56).

Regarding claims 67 and 69, the coating further comprises a linking agent that is placed between the substrate including the base coat and the therapeutic containing layer (col.2, l.62-64). In this embodiment the linking agent is the plurality of monomer molecules and the therapeutic containing layer is the additional

layer. The linking agent comprises a monomer or derivative selected from acrylamide or N,N-dimethylacrylamide (col.9, l.46-56). Therefore, the coating represented by the linking agent layer of Michal et al serves as a tie coat to adhere the additional layer and has functional groups to attach or bind physiologically or pharmacologically active gents.

Regarding claim 68, the top coat is a hydrophilic agent made of acrylamide or N,N-dimethylacrylamide so inherently absorbs large quantities of water to provide moisture absorption or of lubricity.

Regarding claim 70, the coating comprises a drug depot permitting the delivery of drugs form the graft polymer coating (col.4, l.10-65).

Regarding claim 73, the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, l.1-20).

Regarding claims 74 and 75, the device is formed of only the substrate, which is defined as the metal device and base coat comprised, and said coating, which is defined by the top coat in Michal et al.

Regarding claims 76, 83, and 87, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said

substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). The substrate comprises polymers or copolymers of polyolefins or polyamides (col.5, l.34-41). The substrate has either a coating comprising a base coat and top coat system or a coating comprising a coating comprising a grafting component blended with the hydrophilic agent directly grafted to the substrate (col.11, l.17-21 and col.12, l.4-7). In the embodiment in which the coating comprises a base coat and top coat system, the base coat is a plurality of monomer molecules directly graft polymerized on the surface of the substrate, forming a coating thereon, wherein said coating on said substrate is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an alklacrylate such as methacrylate (col.8, l.28-31 and l.50-54).

Regarding claims 77-78 and 88-89, the medical device is a catheter, guide wire or medical instrument (col.2, l.10-12), and the catheter is specifically a PTCA catheter (col.5, l.53-56).

Regarding claims 79 and 90-91, in the embodiment in which the coating is the base coat of the coating system the top coat forms an additional layer and the base coat serves as a tie coat to adhere the additional layer to the substrate. The top coat

comprises a hydrophilic agent which comprises polymers that include acrylics or cellulosics (col.7, l.39-48).

Regarding claims 80 and 92, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating absorbs large quantities of water to provide moisture absorption or of lubricity.

Regarding claims 81 and 93, in the embodiment in which the coating is the base coat of the coating system the top coat is a physiologically or pharmacologically active agent that is bonded to the base coat by the functional groups of the base coat.

Regarding claim 82, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating comprises drugs for delivery within the body, so the coating is a drug depot.

Regarding claims 84 and 94-95, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, l.1-20).

Regarding claims 85-86 and 96-97, in the embodiment in which in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate (col.11, l.17-22 and Figures 5-7), the medical device contains only the substrate and coating.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al (USPN 6,287,285) in view of Goldberg et al (USPN 5,804,263).

Michal et al teach all that is claimed in claim 64 as shown above, but fails to explicitly teach that the substrate comprises silicon polymer. However, Michal et al teaches that the substrate that the top coating is applied to includes high

density polyethylene, polyethylene terephthalate, polyolephinic ionomers, nylon, which is a polyamide, and other polymeric materials which are frequently used to form catheters (col.5, l.38-44). Goldberg et al teach that silicon polymers are widely used for medical tubing and catheters and require hydrophilic surface modification in the same manner as polyolefins and polyurethanes that are used to form catheters (col.9, l.13-44). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that silicon rubber is a polymer frequently used to form catheters and that it requires modification with coatings to provide hydrophilic properties in the same manner as polyolefin and polyurethane based catheters, as taught by Goldberg et al. Furthermore, Applicant has provided no criticality to the selection of silicon polymers over any of the other polymers claimed for forming the substrate.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select silicon polymer as the substrate of the catheter or medical device of Michal et al, because Michal et al desires the catheter or medical device substrate to include any polymer frequently used to form catheters and Goldberg et al teach that silicon polymers are widely used to form catheters.

Response to Arguments

9. Applicant's arguments regarding the 35 U.S.C. 112, first paragraph rejections of record, have been fully considered and are not persuasive, and although the actual claims that were rejected have been cancelled and new ones written, the same rejection still applies.

The broad support described in the arguments do not address the issue raised in the previous Office Action. There is no question generically that there are locations within the specification that teach all of the individual substrates and coating compositions. Neither is there question that there is support for the different uses of the coating. The issue of new matter is with regard to the combinations. Not every individual substrate and coating composition is described as being able to perform every reason for the coating to be applied. In contrast, the specification actually describes to one having ordinary skill in the art that depending on the intended use for the medical device, different coating compositions are selected. Therefore, it is new matter where coating compositions that are not described in the specification as being used in a certain manner are claimed as having the ability to perform that function. It is suggested that the claims be rewritten so that

the specific compositions that are used for specific end results are paired up and not attempt to claim every composition with every function.

In response to Applicant's argument that pyridine and piperidine are not new matter, these compounds were not described in the originally filed specification. By claiming piperidine and pyridine in a Markush group in claim 76, the claim is reciting that piperidine or pyridine is the composition of the coating. However, the original disclosure did not include piperidine or pyridine as being used as a composition of the coating. If it is desired to claim the specific pyridine or piperidine disclosed in the original disclosure then claim them as disclosed and not the broader terms that include compounds that do not have support in the original disclosure.

10. Applicant's arguments regarding the 35 U.S.C. 112, second paragraph rejections of record have been considered but they are moot since the rejections have been withdrawn.

11. Applicant's arguments regarding the 35 U.S.C. 102 rejections of record have been considered but they are not persuasive.

In response to Applicant's argument that Michal does not anticipate claim 37 (not claim 64), claim 37 is broader than applicant is arguing. Applicant is arguing claim 37 as though "substrate" only means a single-layered, object formed from only one material. However, Substrate is not given a specific definition by applicant in Applicant's specification so it must be given its broadest reasonable interpretation. A substrate is merely an underlying support. Substrate is not inherently provided with any additional limitations. Therefore, the scope of the term substrate would include articles such as desks, which would include many different materials, layers, coatings, etc. In the same manner, substrate as claimed by the Applicant given its broadest reasonable interpretation would include the combination of a medical device and base coat taught by Michal et al.

In response to Applicant's argument that Michal does not anticipate claims 44 and 51 (now claims 76 and 89), Applicant did not address the rejections of claims 44 and 51 but instead attempted to include them under the same argument against claim 37. However, claims 44 and 51 were rejected by a different embodiment in Michal et al that did not include the metal device at all and only included a single layered substrate made of a single material.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB CPB
February 10, 2007

ALICIA CHEVALIER
PRIMARY EXAMINER